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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,727	08/24/2001	Reiner L. Gentz	PF454P2	3532
22195	7590	01/28/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	12

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,727

Applicant(s)

GENTZ ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 49-123 are pending in the instant application. Claim 115 has been amended and claims 1, 15, 26, 31, 36 have been canceled as requested by Applicant in Paper Number 10, filed October 29, 2003.

Objection to Specification

2. The objections to the specification are withdrawn in view of Applicants' amendments to the substitute specification, which has been entered.

Withdrawn Claim Objections

3. The objection to the claims is withdrawn in view of Applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 82-114 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record in the previous Office Action, Paper No. 9, at pages 6-7.

Applicants on pages 16-17 of the response state that a copy of the ATCC Deposit for ATCC Accession Numbers 97810 and 97809 are enclosed with the response, however, these documents appear to be missing. The rejection will be withdrawn upon receipt of these documents.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 49-123 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record the Previous Office Action, Paper No. 9, at pages 7-8 (sections 8.1 and 8.2), and below.

Applicants traverse the rejection and assert that the Federal Circuit has repeatedly recognized that claims may use language that those of skill in the art understand without the need for explicit, detailed definitions, and cite *W. L. Gore and Associates v. Garlock, Inc.*, *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.* and *Personalized Media Communications, LLC v. International Trade Comm'n*. Applicants also assert that Section 2173.05 of the M.P.E.P. states that if the specification does not disclose a standard for measuring the term of degree, "a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention." Applicants submit that the phrase "specifically binds", is a term of art which is routinely used, recognized, and understood by those of ordinary skill in the antibody arts, and submit a definition from *Immunology: a Synthesis*, on page 18 of the response, and identify routine assays for identifying a "specific" antibody from *Current Protocols in Immunology*, attached as Exhibit B, and on page 19 of the response, submit that catalogs such as the 1994 Boehringer Mannheim Biochemicals Catalog use the term "specificity" to describe one of the many features of the antibodies which are offered for sale. Applicants further submit

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on pages 19-20 of the response that that while The Catalog does not claim that the “specific” antibodies listed bind the desired protein to the exclusion of all other proteins, it would be clear to one of ordinary skill in the art that these antibodies preferentially bind to their target antigen to the exclusion of non-related proteins, and provide examples of what polypeptides would be bound by an antibody that “specifically binds” a polypeptide of the invention (paragraph bridging pages 19 and 20).

Applicants’ arguments have been fully considered but are not deemed persuasive. None of the references cited provide a clear definition of what “specifically binds” means, and Applicants statement that “it would be clear to one of ordinary skill in the art that these antibodies preferentially bind to their target antigen to the exclusion of non-related proteins” does not clarify the situation. It is not clear *how* related a protein would have to be to the polypeptide of SEQ ID NO: 2 to “specifically bind” an antibody generated against the polypeptide of SEQ ID NO: 2, which makes the claims vague and indefinite.

Applicants also traverse the rejection based on the difference in scope between “binds” and “specifically binds” on pages 20-21 of the response, and assert that 35 U.S.C. § 112, fourth paragraph provides that “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which is refers.”, and that while there is no conflict between the use of the broader term “binds” in the dependent claim (50 for example) because that “binding” is within the scope of the “specific binding” of the antibody of claim 49. Applicants appear to be making the case that a subset of the class of antibodies that specifically bind a protein consisting of amino acids 31-300 of SEQ ID NO: 2 will also bind a fragment of the protein that retains an epitope

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of the larger protein, and that such binding is within the scope of specific binding of the larger protein because the antibody is still recognizing the same protein, albeit a fragment of that protein.

Applicants' arguments have been fully considered but are not deemed persuasive. An antibody that binds an epitope of the larger protein will also bind the same epitope of a fragment of the larger protein to the same extent, so it is not clear what the difference is in scope between the terms "specific binding" and binding. Therefore, the rejections are maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM. *Applicant is advised that effective January 23, 2004,, the Examiner's phone number will be (571) 272-0878.*

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564. *Applicant is advised that effective January 23, 2004, Yvonne Eyler's phone number will be (571) 272-0871.*

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Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600